PSJ11 CVS Opp Exh 17

From:	Nicastro, MArk T. </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MTNICASTRO>
To:	'Gillen, Daniel J.'
CC:	Nicastro, MArk T.
Sent:	11/21/2013 11:39:50 AM
Subject:	Closing meeting
Attachments:	Definition of Metrics for SOM analysis.xlsx; Letter to Mr. Gillen November 21, 2013.docx; NEJM abusive prescribing cvs data.pdf; SOM SOP v 3.docx; Stopped orders.xlsx

Hello Dan,
I apologize for all the attachments, but the information I have included provides a clear strategy on how we manage suspicious orders.
-The first file is my formal request for a closing and why we want to move forward. There is also information about our SOM process included.
-The second file is a list of metric definitions we use as part of our SOM analysis.
-The third file is our Standard Operating Procedure for SOM.
-The fourth file is a list of stores where we have stopped orders.
-The fifth file is an article penned by two executives of CVS Caremark which was published by the New England Journal of Medicine in August of 2013.

Please contact me with any questions you may have.
Thank you,

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Indianapolis Distribution center
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November 21, 2013

Dear Mr. Gillen,

I am following up on our conversation the other day and our email exchange. Since our compliance audit in August 2013, we have been looking forward to the closing audit for formal comments and recommendations from the DEA. At this time, I would formally request that the DEA set a date for the closing meeting at the Indianapolis DC. I have added the following body of information to support my request to move forward.

As noted during the audit, CVS is in the process of updating its SOM processes. We would like to incorporate any recommendations resulting from the DEA inspection into our SOM Standard Operating Procedures (SOP's), prior to finalizing the update. In our conversation on November 14, you mentioned that you had concerns about our SOM process, specifically stating that you were going to report to your Program Manager in Chicago that we have no reporting structure in place. To continue the positive relationship we have had with your office, we want to engage you on your concerns and would welcome feedback from this audit to implement in our updates.

As we demonstrated during the audit with DEA Diversion Investigators Andrew Ratcliff and Michael Feraldo, CVS has a robust SOM process and we take our obligations seriously. We walked the Investigators through the SOM process and showed them some of the orders that have been reviewed while they were on site. Their comments were favorable. We empower our associates in the facility to notify management of any irregularities so an order can be reviewed before the controlled substance is shipped. As you know, Matt Murphy's Pharma Compliance Group has been working with the SOM group since our SOM manager resigned. We have retired DEA Investigators on site as they assist in the daily SOM review.

I gave your Investigators a copy of our SOM Standard Operating Procedure (SOP) during the discussion of our SOM and I have attached a copy for your review, but below are the highlights of our process:

- We have algorithms through which all controlled substance orders are run.
- It was developed and implemented in 2008 to identify controlled substance orders of unusual size, unusual frequency, and orders that deviate from a normal buying pattern.

Any order that is flagged by our SOM model or questioned by our DC team is initially identified as an "order of interest" and has additional due diligence conducted by the SOM team. Our SOM system has been continuously modified and enhanced with additional evaluative criteria and parameters to detect suspicious orders. Due diligence on orders of interest may include:

- contacting the store and speaking to the pharmacist
- reviewing prior ordering data
- comparing ordering and dispensing data
- comparing the quantity of controlled substances to non-controlled substances
- determining if prescriptions for "drug cocktails" are being presented to the store
- determining if one or several doctors make up a disproportionate share of the dispensing
- review of the store's ordering vs. dispensing
- review of potential patients/prescribers of concern such as:
    - Common doctor
    - Patient age
    - Dispensing quantity
    - Payment method
    - Distance traveled

While our additional due diligence is being conducted, the order for the identified drug family is held at the DC. CVS will only release a held order if we are able to ensure that it was placed for legitimate dispensing purposes. If our due diligence identifies an order as suspicious, it is cancelled and reported to the registrants DEA office. CVS will not resume shipping that drug family to the identified store until a full investigation is completed and remediation plans are implemented to ensure all CVS policies and procedures are being followed.

I explained during the DEA visit that as part of our "know your customer" CVS has twice the market share in Indiana of any other pharmacy. When we review general market share data, CVS had a [redacted] market share for all drugs in the second quarter of 2013. In comparison, chains—excluding CVS—had a [redacted] market share. Moreover, our market share for hydrocodone is about the same as our general markets share during the same time period—[redacted]. Interestingly, chains excluding CVS index higher for hydrocodone than all other drugs—[redacted] market share. Thus, other chains are dispensing more hydrocodone in proportion to other drugs than CVS is. Given the market shares, you would expect that CVS would ship approximately twice the amount of hydrocodone, but that is not the case.

More interesting facts for Indiana:

- The vast majority of dispensing is for original prescriptions [redacted] by prescription count) with roughly [redacted] of prescriptions being written for quantities of thirty tablets or less. Both of these statistics indicate dispensing for acute care. Dispensing is equally spread amongst strengths.
- [redacted] of hydrocodone prescriptions are dispensed for patients older than 35, [redacted] for patients between the ages of 18-35, [redacted] for patients less than 18.
- [redacted] of prescriptions for hydrocodone are dispensed to residents of the state of Indiana.

In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited number of suspicious orders identified through our distributor SOM process.

For your information, I have also attached an article published from the New England Journal of Medicine concerning one program that CVS administers concerning prescriber review. I am happy to facilitate a discussion with the people who manage this program if you would like to learn more.

Please let me know what additional information we can provide to you so we can expedite the closing meeting. As we have discussed, your Investigators did a thorough review of the SOM process while on site. CVS has a complete and compliant SOM process. We used experts in the industry to set it up, and we use experts in the industry to update and review it continuously. I look forward to hearing from you regarding the scheduling of our closing meeting.

Respectfully,
Mark Nicastro

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[redacted]

Geographic zone definitions

Zone 1	CT, MA, ME, NH, RI, VT
Zone 2	NJ, NY, OH, PA
Zone 3	DC, DE, MD, VA, WV
Zone 4	AL, AR, LA, MS, OK, TX
Zone 7	IL, IN, MI, MN, MO, WI
Zone 8	GA, KY, NC, SC, TN
Zone 12	FL
Zone 14	AK, AZ, CA, CO, HI, ID, NM, NV, OR, UT, WA, WY
Zone 18	IA, KS, MT, ND, NE, SD
Zone 20	PR

	CVS / Corporate Logistics External Documents	SOM Process – Stop Order / Order Resumption SOP
	Current Revision Date: **01/10/2013**	**Revision Number 03**

1. **Purpose**:

To detail the three phase approach developed to effectively identify, review and stop potentially irregular orders of PSE or control substance drugs identified by the CVS/Caremark Suspicious Order Monitoring (SOM) process, as well as report orders that are deemed to be suspicious.

2. **Scope**:

This policy and procedure applies to the SOM Analyst, SOM Manager, SOM Review Team, Distribution Center, Loss Prevention, Logistics, and Pharmacy Operations. This policy assigns responsibilities to each team as it applies to the Stop Order / Order Resumption SOP.

3. **Policy**:

The Stop Order / Order Resumption process consists of three phases: Identify and Hold, Review and Research, and Action and Resumption.

- Identify and Hold Phase – Responsible Parties:
  - SOM Analyst
  - SOM Manager
  - Distribution Center
- Review and Research Phase – Responsible Parties:
  - SOM Manager
  - SOM Review Team (SOM Team consists of a delegate from the following departments: Logistics Operations, Pharmacy Operations, Loss Prevention, Compliance, and Legal)
- Action and Resumption Phase – Responsible Parties:
  - SOM Manager
  - Distribution Center
  - Loss Prevention
  - Pharmacy Operations
  - SOM Review Team

4. **Process**:

This process was developed in order to document the appropriate steps to effectively identify, stop, review, and report to the DEA any order of PSE and/or controlled substance drugs identified as suspicious. This process consists of three phases:

- Identify and Hold Phase

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The purpose of the Identify and Hold phase is to identify potentially irregular orders and place a Hold on those orders at the Distribution Center. All orders identified as potentially irregular are labeled "orders of interest" unless determined to be suspicious following the initial due diligence process. Orders of interest are identified by the SOM Analysts while reviewing the PSE Item Review Report (IRR), the Control IRR, and/or the Florida 5000 Dose Report (FRR) or by warehouse employees reviewing or packing orders for distribution to CVS stores.

Once an order of interest is identified, the SOM Analyst will complete all necessary due diligence and the SOM Manager will be notified to review the order. Due diligence will include, but is not limited to: contacting the Pharmacist, reviewing dispensing data, reviewing prior ordering data, comparing the quantity of controlled substances to non-controlled substances, determining if prescriptions for cocktails are being presented to the store, determining if one or several doctors make up a disproportionate share of the dispensing at the pharmacy, and contacting pharmacy operations to verify the information received from the store and to obtain any relevant information they may have about prescribers, nearby clinics, changes in the competitive landscape, or changes in circumstances such as a new emergency room or clinic opening nearby that might impact the ordering history. If the SOM Manager agrees that the order is an order of interest, the Distribution Center will be contacted, both by email and telephone, by the SOM Manager to place a Hold on the drug family in question on the order of interest and the SOM Manager will communicate to the Distribution Center each day to hold future orders for the store in question until the order of interest is verified. Once the order of interest is placed on hold, the process enters phase two, Review and Research.

- Review and Research Phase

Once in the Review and Research Phase, the SOM Manager will inform the SOM Review Team that an order of interest has been identified and a meeting will be scheduled to relay to the SOM Review Team all facts and due diligence completed. The SOM Review Team will discuss the information relayed by the SOM Manager and determine if the order of interest is suspicious.

Once the SOM Review Team has determined the order of interest to be or not to be suspicious, recommendations will be made and phase three, Action and Resumption, is entered.

- Action and Resumption Phase

If the order of interest is NOT determined to be suspicious, the following steps, but not limited to, will be taken:
  - The SOM Manager will contact the Distribution Center and instruct them to pick and ship the order.
  - The SOM Manager will maintain a file that will document the reasons why the order was not considered suspicious, along with all due diligence documentation.
  - The SOM Manager will continue to monitor the store in question to ensure no further orders of concern are identified.

If the order of interest is determined to be suspicious, the following steps, but not limited to, may be taken:
  - The SOM Manager will contact the Distribution Center and instruct to:
    - Cancel the items previously held (including all orders in the same family group by the store in question).
    - Complete a Mark Out on all items to be stopped (all items in ordered for the family group in question).
    - Provide the SOM Manager with a copy of the Quality Scan for the tote containing the suspicious order (family group).

  - Discontinue shipping the drug family in question to the store in question until further instruction is received.
- The SOM Manager will contact Pharmacy Operations to inform them of the stopped order and to request that the store in question be contacted inform it not to order the items (family group) in question.
  - The SOM Manager is to receive confirmation from Pharmacy Operations that the store will not order the items (family group) until it receives further notification. If the store in question does order the items (family group), it will be told to quarantine the items (family group).
  - This documentation is to be maintained with all due diligence documentation related to the store in question.
- The SOM Manager will monitor future orders from the store in question and communicate to the Distribution Center to stop the drug family in question.
  - This process will continue until the decision is made to resume shipping the drug family in question to the store in question.
- The SOM Manager will immediately contact the local DEA field office for the store in question, via facsimile, to notify DEA of the suspicious order. If applicable, notification should also be sent to the Board of Pharmacy.
- If the suspicious order was for a listed chemical, the SOM Manager must file a written report with the local DEA filed office within 15 days explaining the circumstances of the order. A copy of the report filed with DEA must be maintained and a copy sent to Regulatory Compliance.
- Based on recommendation from SOM Review Team, Loss Prevention may communicate to Regional Loss Prevention Manager to complete an LP Review at the store in question.
  - The LP Manager will submit a report of their findings to the SOM Manager/Analyst within 24 hours of their Review.
- Based on recommendation from SOM Review Team, Pharmacy Operations may schedule the store in question for a Pharmacist Review Panel or an investigation.
- Based on recommendation from SOM Review Team, Pharmacy Operations may contact the Pharmacy Supervisor of the store in question and ensure the remediation plan is completed.

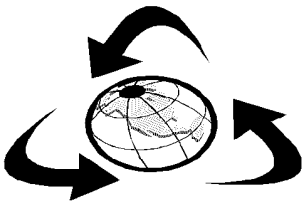
All documentation from reviews, investigations, training, etc. will be forwarded to and maintained by the SOM Manager.

Once the steps for orders determined to be suspicious have been completed and steps have been taken to resolve any concerns about the store, the SOM Manager will contact the Distribution Center and instruct them to resume shipping the drug family in question to the store in question. Pharmacy Operations may inform the store that it can order from the Outside Vendor to order if necessary. The SOM Manager will also continue to monitor the store in question to ensure no further orders of concern are identified.

Revision Documentation:

Revision Number	Date Revised	The following has been revised…
01	01/07/2013	Creation
02	01/10/2013	All
03	8/4/2013	reviewed

Approved by: Management Representative	**Date Approved:**
Signature:	

	**CVS / Corporate Logistics** External Documents	**SOM Process – Stop Order / Order Resumption SOP**
	Current Revision Date: **01/10/2013**	**Revision Number** **03**

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Date	Store #	Address	DEA contact
2/29/2012	7455	700 W Seminary Drive Fort Worth, Texas	Joel Dunn
11/21/2012	9199	5420 Dewey Drive Fair Oaks, CA	Mark Jackson
11/21/2012	9884	2601 Oakdale Road Modesto, CA	Mark Jackson
11/21/2012	9919	700 W Seminary Drive Fort Worth, Texas	Mark Jackson
10/1/2013	3059	Longs drugs 55 Kiopa Street Pukalani, HI	Michael Lewis (LA Office)
10/1/2013	4496	Longs drugs 1900 Main Street Wailuku, HI	Michael Lewis (LA Office)
10/7/2013	4492	Longs drugs 41 East Lipoa Street Kihei, HI	Michael Lewis (LA Office)

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Abusive Prescribing of Controlled Substances — A Pharmacy View

Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H

Public health advocates are increasingly focused on illness and deaths caused by inappropriate use of controlled substances — in particular, opioid analgesics. Opioid prescriptions have increased dramatically, by more than 300% between 1999 and 2010.[1] This increase has led to substantial iatrogenic disease. Most strikingly, the number of deaths due to overdose in the United States increased from 4000 in 1999 to 16,600 in 2010.[2] Indeed, overdose is now the second-leading cause of accidental death in this country, where more than 2.4 million people were considered opioid abusers in 2010.[3]

The causes of increases in prescriptions and the prevalence of abuse are manifold. In the mid-1990s, advocates for treatment of chronic pain began arguing that pain was largely undertreated and appropriately exhorted clinicians to be more liberal in their treatment. In addition, a number of new formulations of opioid agents became available, with purported advantages in analgesia.

But perhaps just as important, inappropriate prescribing has grown. The worst form of such prescribing occurs in so-called pill mills, wherein fully licensed physicians with valid Drug Enforcement Administration (DEA) numbers write prescriptions that provide large quantities of powerful analgesics to individual patients. Such bogus pain clinics cater to younger patients, operate on a cash basis, and draw clients from a broad geographic area. States and the DEA have attempted to curb pill-mill activities — the best example being Florida's closure of 254 "pain clinics" — but the efficacy of such regulation is unclear.[4]

Pharmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular. Under the Controlled Substances Act, pharmacists must evaluate patients to ensure the appropriateness of any controlled-substance prescription. In addition, state boards of pharmacy regulate the distribution of opioid analgesics and other controlled substances through the discretion of pharmacists. Yet in the majority of cases of potential abuse, pharmacists face a patient who has a legal prescription from a licensed physician, and they have access to very little other background information. That makes it difficult for individual pharmacists to use their own partially informed judgment to identify prescriptions that have come from a pill-mill doctor.

Chain pharmacies, however, have the advantage of aggregated information on all prescriptions filled at the chain. At CVS, we recently instituted a program of

Prescribing Habits of Outlier Prescribers.

Specialty or Type of Clinician	Average Monthly Doses of High-Risk Drugs Prescribed		No. of Outlier Prescribers
	42 Outlier Prescribers	Nonoutlier Prescribers	
Internal medicine	11,314	422	12
Physical medicine	5,599	916	1
Family practice	12,903	575	8
General practice	24,502	462	2
Psychiatry	18,757	213	3
Nurse practitioner	10,715	160	2
Obstetrics and gynecology	11,096	110	3
Physician assistant	5,211	116	1
Pain medicine	8,811	3,813	1
Sports medicine	7,025	387	1
Pediatrics	5,524	31	2
Anesthesiology	8,128	1,749	1
Geriatric medicine	15,544	493	1
Endocrinology	6,142	116	1
Emergency medicine	7,935	203	2
Preventive medicine	44,397	662	1

analysis and actions to limit inappropriate prescribing. Our program was intended to identify and take action against physicians and other prescribers who exhibited extreme patterns of use of "high-risk drugs" relative to other prescribers. We aimed to minimize the potential for falsely identifying legitimate prescribers (false positives), accepting that doing so might result in a failure to identify some suspicious prescribers.

We identified high-risk prescribers by benchmarking them against others on several parameters. We used data from submitted prescriptions from March 2010 through January 2012 for hydrocodone, oxycodone, alprazolam, methadone, and carisoprodol. Prescribers were compared with others in the same geographic region who had the same listed specialty. The first parameters were the volume of prescriptions for high-risk drugs and the proportion of the prescriber's prescriptions that were for such drugs, as compared with the volume and proportion for others in the same specialty and region; the thresholds for suspicion were set at the 98th percentile for volume and the 95th percentile for proportion. Next, prescribers were evaluated with regard to the number of their patients who paid cash for high-risk–drug prescriptions and the percentage of their patients receiving high-risk drugs who were 18 to 35 years of age. In both cases, the thresholds for suspicion were set at the 90th percentile among clinicians in the same region and specialty. Finally, we compared the prescriptions for noncontrolled substances with the prescriptions for controlled substances within the prescriber's practice on the same parameters. To minimize the possibility that we would suspend dispensing privileges for clinicians who were appropriately treating patients, we attempted to interview physicians whom we'd identified as outliers to ascertain the nature of their practice and their use of controlled substances.

We initially identified 42 outliers (see table) from our database of nearly 1 million prescribers; 17 of the 42 failed to respond to our three letters requesting an interview, despite our indication in the second and third letters that we would stop filling the clinician's controlled-substance prescriptions if he or she would not speak with us. Eight prescribers sent a written response, and one response was sufficiently detailed to convince us that the prescribing was appropriate. The other seven responses were inadequate, and the prescribers refused to engage in a telephone discussion. Two prescribers retained an attorney, and future conversation occurred through legal channels. We considered these 26 clinicians nonresponsive.

The remaining 15 were contacted by phone, and 5 gave us legitimate reasons why their practice had the identified characteristics — in particular, that each was the only practitioner in a given geographic area caring for patients with chronic pain. The remaining 10 either maintained that their approach was legitimate but that they didn't have to explain why or averred that they planned to curb their prescribing of narcotics. For all 10 of these clinicians, we decided not to fill their controlled-substance prescriptions through our pharmacy. The same approach was taken for the 26 nonresponsive clinicians. Surprisingly, now 9 months after we stopped filling controlled-substance prescriptions for these

clinicians' patients, we've had contact from only 3 of them requesting reinstatement in our pharmacy chain. The table provides details on the 42 outliers' practices, as compared with those of the average prescriber in our database. There was no clear regional concentration of outliers.

Our program is certainly not a comprehensive solution, but it provides some sense of the kind of inappropriate prescribing that is going on in our health care system. We believe that some of these clinicians may be part of pill mills, doing cursory examinations in high volumes of patients, all of whom then receive opioid analgesics. People seeking to abuse these medications will travel long distances to obtain them and often deal in cash only. These patients are generally younger than the average patient with chronic disease. A comprehensive solution would involve the use of a national prescription-drug–monitoring database that would be used by clinicians at the point of prescribing and by all pharmacies at the point of dispensing. This enhanced view of a patient's controlled-substance history and behaviors would support both prescribers and pharmacists in applying their professional judgment regarding the appropriateness of dispensing a controlled substance.

As we noted, pharmacists have an ethical duty, backed by both federal and state law, to ensure that a prescription for a controlled substance is appropriate. A young person traveling a good distance to fill a prescription and paying cash should raise some concerns for a pharmacist. If the prescription is valid, the pharmacist might have limited grounds on which to deny medication to someone who might be in pain. Yet the DEA has now identified both pharmaceutical distributors and chain pharmacies as part of the problem,[5] encouraging our industry to develop new programs to reduce inappropriate use.

Our findings provide a lens into the problem we face as a country. Programs providing greater transparency regarding controlled-substance prescribing, such as mandatory use of e-prescribing for all controlled substances and a national, uniform program of prescription-drug monitoring, would help pharmacists and clinicians target interventions more accurately to help patients who are abusing medications. Some state solutions, such as the Massachusetts database that allows clinicians to look up their own patients' prescriptions, also have merit. Analyses of aggregated data like ours can also target patterns of abuse by both prescribers and patients. Given the growing use of controlled substances and the resulting illness and deaths, more innovative use of transparent data is only prudent.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From CVS Caremark, Woonsocket, RI.

This article was published on August 21, 2013, at NEJM.org.

1. Kunins HV, Farley TA, Dowell D. Guidelines for opioid prescription: why emergency physicians need support. Ann Intern Med 2013;158:841-2.
2. Dowell D, Kunins HV, Farley TA. Opioid analgesics — risky drugs, not risky patients. JAMA 2013;309:2219-20.
3. Lembke A. Why doctors prescribe opioids to known opioid abusers. N Engl J Med 2012; 367:1580-1.
4. Rosenau AM. Guidelines for opioid prescription: the devil is in the details. Ann Intern Med 2013;158:843-4.
5. Drug Enforcement Administration. DEA serves another Walgreens pharmacy an order to show cause. February 6, 2013 (http://www.justice.gov/dea/divisions/mia/2013/mia020613.shtml).

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